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10/694,685	10/28/2003	Andrzej S. Krolewski	10276-078001 / JDP-078	4057	
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	LIS, MN 55440-1022		ART UNIT	PAPER NUMBER	
			1634		

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)
Office Action Summary		10/694,685	KROLEWSKI ET AL.
		Examiner	Art Unit
		Jehanne S. Sitton	1634
Period fo	The MAILING DATE of this communication ap		
A SH WHIC - Exte after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPLICED FOR INC.  CHEVER IS LONGER, FROM THE MAILING INC.  SIX (6) MONTHS from the mailing date of this communication.  Depriod for reply is specified above, the maximum statutory period re to reply within the set or extended period for reply will, by statufing reply received by the Office later than three months after the mailined patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNICATIO .136(a). In no event, however, may a reply be tid d will apply and will expire SIX (6) MONTHS from te, cause the application to become ABANDONI	N. mely filed  n the mailing date of this communication. ED (35 U.S.C. § 133).
Status			
2a) <u></u> ☐	Responsive to communication(s) filed on 28 C.  This action is <b>FINAL</b> . 2b) This Since this application is in condition for allowed closed in accordance with the practice under	is action is non-final. ance except for formal matters, pr	
Dispositi	on of Claims		
5)□ 6)□ 7)□ 8)⊠ <b>Applicati</b> 9)□	Claim(s) 1-45 is/are pending in the application 4a) Of the above claim(s) is/are withdra Claim(s) is/are allowed. Claim(s) is/are rejected. Claim(s) is/are objected to. Claim(s) 1-45 are subject to restriction and/or on Papers The specification is objected to by the Examin The drawing(s) filed on is/are: a) according a content of the drawing(s) filed on is/are: a)	even from consideration.  relection requirement.  er.  cepted or b) objected to by the	
11)□	Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the E	ction is required if the drawing(s) is ob	ojected to. See 37 CFR 1.121(d).
Priority u	ınder 35 U.S.C. § 119		
12) a)[	Acknowledgment is made of a claim for foreign All b) Some * c) None of:  1. Certified copies of the priority documen 2. Certified copies of the priority documen 3. Copies of the certified copies of the priority application from the International Bureasee the attached detailed Office action for a list	nts have been received. Its have been received in Applicatority documents have been received (PCT Rule 17.2(a)).	ion No ed in this National Stage
2) 🔲 Notic 3) 🔲 Inforr	t(s) e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08 r No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail D  5) Notice of Informal F  6) Other:	

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## **DETAILED ACTION**

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## Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-22, 35, and 36, drawn to T2DM1 nucleic acids, vectors and host cells, classified in class 536, subclass 23.1, class 435, subclass 320.1, and class 435, subclass 325, respectively (this group is subject to further restriction).
  - II. Claims 1-22, 35, and 36, drawn to T2DM2 nucleic acids, vectors and host cells, classified in class 536, subclass 23.1, class 435, subclass 320.1, and class 435, subclass 325, respectively (this group is subject to further restriction).
  - III. Claims 23-24, drawn to a polypeptide of SEQ ID NO: 2, classified in class 530, subclass 350.
  - IV. Claims 23-24, drawn to a polypeptide of SEQ ID NO: 4, classified in class 530, subclass 350.
  - V. Claim 25, drawn to an antibody which binds SEQ ID NO: 2, classified in class 530, subclass 387.1.
  - VI. Claim 25, drawn to an antibody which binds SEQ ID NO: 4, classified in class 530, subclass 387.1.
  - VII. Claim 45, drawn to a transgenic animal comprising a T2DM1 transgene, classified in class 800, subclass 8.
  - VIII. Claim 45, drawn to a transgenic animal comprising a T2DM2 transgene, classified in class 800, subclass 8.

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IX. Claim 26, drawn to a method of producing a polypeptide, classified in class 435, subclass 71.1 (this group is subject to further restriction).

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- X. Claims 27-28, 32 and 34, in part, drawn to a method of determining if a subject is at risk for diabetes, comprising evaluating the level or expression of a T2DM1 molecule, classified in class 435, subclass 6 or 7.1.
- XI. Claims 27-28, 32 and 34, in part, drawn to a method of determining if a subject is at risk for diabetes, comprising evaluating the level or expression of a T2DM2 molecule, classified in class 435, subclass 6 or 7.1.
- XII. Claims 27 and 28, in part, drawn to a method of determining if a subject is at risk for diabetes comprising evaluating the activity of a T2DM1 molecule, classified in class 514, subclass 1.
- XIII. Claims 27 and 28, in part, drawn to a method of determining if a subject is at risk for diabetes comprising evaluating the activity of a T2DM2 molecule, classified in class 514, subclass 1.
- XIV. Claims 27-34 and 37, in part, drawn to a method of evaluating a genotype of a T2DM1 nucleic acid, classified in class 435, subclass 91.2 (this group is subject to further restriction).
- XV. Claims 27-34, and 37, in part, drawn to a method of evaluating a genotype of a T2DM2 nucleic acid, classified in class 435, subclass 91.2 (this group is subject to further restriction).

- XVI. Claim 38, in part, drawn to a method of detecting the presence or absence of two or more polymorphisms in a T2DM1 nucleic acid, classified in class 435, subclass 91.2.
- XVII. Claim 38, in part, drawn to a method of detecting the presence or absence of two or more polymorphisms in a T2DM2 nucleic acid, classified in class 435, subclass 91.2.
- XVIII. Claims 39-41, in part drawn to a method of treating a subject comprising modulating the level or expression of a T2DM1 molecule in a subject, classified in class 514, subclass 44.
- XIX. Claims 39-41, in part drawn to a method of treating a subject by modulating the activity of a T2DM1 molecule in a subject, classified in class 514, subclass 1.
- XX. Claims 39-41, in part, drawn to a method of treating a subject by modulating the level or expression of a T2DM2 molecule of a subject, classified in class 514, subclass 44.
- XXI. Claims 39-41, in part, drawn to a method of treating a subject by modulating the activity of a T2DM2 molecule of a subject, classified in class 514, subclass 1.
- XXII. Claims 42-44, in part, drawn to a method of screening for a compound that affects type 2 diabetes susceptibility using a T2DM1 nucleic acid, classified in class 536, subclass 18.5.
- XXIII. Claims 42-44, in part, drawn to a method of screening for a compound that affects type 2 diabetes susceptibility using a T2DM2 nucleic acid, classified in class 536, subclass 18.5.

XXIV. Claims 42-44, in part, drawn to a method of screening for a compound that affects type 2 diabetes susceptibility using a T2DM1 protein, classified in class 436, subclass 501.

- XXV. Claims 42-44, in part, drawn to a method of screening for a compound that affects type 2 diabetes susceptibility using a T2DM2 protein, classified in class 436, subclass 501.
- 2. Additionally, certain groups named above are subject to further restriction as follows:

For groups I or II, applicant is required to further elect a nucleic acid from SEQ ID NO 1 or 3 (structurally distinct T2DM1 nucleic acids) or: SEQ ID NO 5 or 6 (structurally distinct T2DM2 nucleic acids), for search and examination of claims 1-5, 22. Although claims 35 and 36 do not recite any specific SEQ ID NOS and will therefore not be limited to a particular nucleic acid in search and examination unless amended to a specific SEQ ID NO:, they will be limited for search and examination to T2DM1 or T2DM2 depending on which SEQ ID NO: is elected for claims 1-5 and 22. For claims 6-21, applicant is required to elect one oligomer (that is, one of SEQ ID NOS 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, or 36, each of which is drawn to a structurally distinct nucleic acid comprising a structurally different polymorphism) that corresponds to the elected SEQ ID NO with regard to claims 1-5 and 22. With respect to claims 6-21, any claim which recites a non elected oligomer will be withdrawn from consideration as being drawn to a non elected invention.

For group IX, applicant is required to further elect a nucleic acid from SEQ ID NOS 1, 3, 5, or 6 for search and examination of claim 26.

For groups XIV and XV, applicant is required to further elect a structurally distinct polymorphism for search and examination of claim 31. Claims 27-30 drawn to methods of genotyping, links the polymorphisms in claim 31. The restriction requirement among the linked inventions (polymorphisms) is subject to the nonallowance of the linking claim(s), claims 27. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

This additional restriction requirement is NOT an election of species. The nucleic acids are structurally and functionally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to restriction

requirement pursuant to 35 USC 121 and 37 CFR 1.141. By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant... to elect that invention to which his claim shall be restricted." 37 CFR 1.142 (a). See also 37 CFR 1.141(a). It is noted that searching more than indicated structurally distinct sequences represents a serious burden for the office.

3. The inventions are distinct, each from the other because of the following reasons:

The inventions of groups I-VIII are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acid of groups I and II are composed of deoxyribonucleotides linked by phosphodiester bonds and assumes the form of a double helix. The polypeptide of groups III and IV are composed of amino acids linked by peptide bonds and can assume complex tertiary structures. While the antibody of groups V and VI are also composed of amino acids linked by peptide bonds, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associate via disulfide bonds into a Y-shaped symmetric dimer. The transgenic animal of group VII and VIII is made up of tissue and organ systems which make up an organism. The products of groups I-VIII can be used in materially different processes, for example the DNA of groups I and II can be used in hybridization assays, the antibody of groups V and VI can be used in immunoassays, and the polypeptide of group III and IV can be used to make a fusion protein

with an enzymatic function, while the transgenic animals of groups VII and VIII can be used to make animal models. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of groups I-VIII are patentably distinct from each other. The search for each of groups I-VIII presents a serious search burden as the searches for each are not coextensive in scope. The inventions have different status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies. Furthermore, antibodies which bind to an epitope of a polypeptide may be known even if the polypeptide is novel. Additionally, art relating to nucleic acids, proteins, or antibodies would not necessarily provide any information regarding transgenic animals, and vice versa. Searching, therefore is not coextensive.

The inventions of groups I& II are directed to structurally and functionally distinct nucleic acid molecules. The inventions of groups III and IV are directed to structurally and functionally distinct polypeptides. The inventions of groups V and VI, are directed to structurally and functionally distinct antibodies as they detect structurally distinct polypeptides. The

inventions of groups VII & VIII are directed to structurally and functionally distinct transgenic animals which contain structurally and functionally distinct transgenes. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141. By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant... to elect that invention to which his claim shall be restricted." 37 CFR 1.142 (a). See also 37 CFR 1.141(a). It is noted that searching more than indicated structurally distinct sequences represents a serious burden for the office.

Inventions X & XI, XII & XIII, XIV & XV, XVI & XVII, XVIII & XX, XIX & XXI, XXII & XXIII, XXIV & XXV are directed to related methods which differ in T2DM1 vs T2DM2 molecules. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods do not overlap in scope and are directed to either T2DM1 or T2DM2 which are structurally and functionally distinct, the methods are not obvious variants, the methods are not capable of use together and have materially different design. A search burden exists for searching each of the inventions because art relating to T2DM1 molecules will not necessarily

provide any information on a structurally and functionally different molecule: T2DM2. Searching is not coextensive.

Inventions X (XI), XII(XIII), XIV (XV), and XVI (XVII) are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods are mutually exclusive as the methods of detecting expression or levels, vs activity, vs genotyping at one position vs genotyping a multiple positions do not overlap in scope, are not capable of use together, have materially different design (measuring the level or expression of a nucleic acid, vs detection of activity of a protein, vs detection of a specific polymorphism in a sequence), mode of operation, and functions. A search burden exists for searching each of the patentably distinct inventions because art relating to methods of expression detection would not necessarily provide any information regarding activity determination or genotyping or haplotyping, and vice versa. Searching is therefore not coextensive.

Inventions XVIII (XX), and XIX (XXI), are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods are mutually exclusive as the methods of modulating the expression of a T2DM1 (T2DM2) molecule vs modulating it's activity do not overlap in scope, are not capable of use together, have materially

different design, mode of operation, and functions. A search burden exists for searching each of the patentably distinct inventions because art relating to modulating expression of a T2DM1 (T2DM2) molecule would not necessarily provide any information directed to modulating it's activity. Searching is not coextensive.

Inventions XXII (XXIII) and XIV (XV) are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods are mutually exclusive as the methods of screening compounds using a nucleic acid vs a protein do not overlap in scope, are not capable of use together, have materially different design, mode of operation, and functions. A search burden exists for searching each of the patentably distinct inventions because art related to screening methods using nucleic acids would not necessarily have any information regarding screening with proteins and vice versa. Searching is not coextensive.

Inventions IX, X-XVII, XVIII-XXI, and XXII-XXV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together, have different designs, modes of operation, and effects (method of producing a polypeptide, vs method of detecting level, activity or genotyping a nucleic acid, vs methods of treating, vs methods of screening for compounds).

The inventions of groups I (II) and X (XI), XIV-XVII, XIX (XX), and XXII (XXIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the nucleic acids can be used to express proteins which is not required to practice the methods of inventions X (XI), XIV-XVII, XIX (XX), and XXII (XXIII). The search for each group presents a serious search burden as the searches for each are not coextensive in scope. Art relating to methods of detecting polynucleotides would not necessarily provide descriptive sequence information on the polynucleotide itself, and vice versa.

The inventions of groups I (II) and IX. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the nucleic acids can be used to make probes and primers for nucleic acid detection which are not required to practice the method of Group IX. The search for each group presents a serious search burden as the searches for each are not coextensive in scope. Art relating to methods of producing polypeptides would not necessarily provide descriptive sequence information on the polynucleotide itself, and vice versa.

The inventions of groups III (IV) and the inventions of groups X (XI), XII (XIII), XVIII (XX), XIX (XXI), and XXIV (XV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using

the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the polypeptides can be used to make fusion proteins with enzymatic properties which are not required to practice the methods of groups X (XI), XII (XIII), XVIII (XX), XIX (XXI), and XXIV (XV). Art relating methods of polypeptide detection or treatment would not necessarily provide any structural information on the polypeptide itself and vice versa. Searching is therefor not coextensive.

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The inventions of groups V (VI) and the inventions of groups X (XI), XVIII (XX), XIX (XXI) and XXIV (XV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the antibodies can be used to illicit an immune response which is not required to practice the methods of groups X (XI), XVIII (XX), XIX (XXI) and XXIV (XV). Art relating methods of using antibodies would not necessarily provide any structural information on the antibody itself and vice versa. Searching is therefor not coextensive.

All other combinations of products and methods are unrelated as they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06).

4. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

- 5. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.
- 6. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
- 7. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

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8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined.

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See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re

Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to

retain the right to rejoinder in accordance with the above policy, Applicant is advised that the

process claims should be amended during prosecution either to maintain dependency on the

product claims or to otherwise include the limitations of the product claims. Failure to do so

may result in a loss of the right to rejoinder.

10. Any inquiry concerning this communication or earlier communications from the

examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-

0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and

on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Ram Shukla, can be reached on (571) 272-0735. The fax phone number for this

Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding

should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jehanne Sitton

**Primary Examiner** 

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6/26/06